Comparison of the effect of breast feeding, sucking the pacifier and being in mother’s hug on pain during infant’s immunization injection

Protocol summary

Summary
The objective of this study was to examine the pain relieving effect of breast-feeding, pacifier use or being in mother’s hug and routine of health centers clinics during immunization injections in healthy neonates. This controlled trial study, was performed on 152 healthy term infants with 2-4 months old, which was brought to the health centers of Iran University of Medical Sciences in west of Tehran by their mother and had DPT immunization. One group were breast-fed, 2 minutes before, during, and 15 seconds after the injection, and second group were used pacifier while held by mothers, 2 minutes before, during, and 15 seconds after the injection, third group were in their mother’s hug 2 minutes before, during, and 15 seconds after the injection and control group according to routine clinic lied on the examining table. Objective changes in appearance of Neonates were assessed by Modified Behavioral Pain Scale.

General information

Acronym
IRCT registration information
- IRCT registration number: IRCT201008284002N2
- Registration date: 2010-09-23, 1389/07/01
- Registration timing: retrospective

Registrant information
- Name: Shadab Shahali
- Name of organization / entity: Academic centre of education, culture and research (ACECR), Iran University of medical sciences bran
- Country: Iran (Islamic Republic of)
- Phone: +98 21 8879 7403
- Email address: shahali@irmed.org

Recruitment status
Recruitment complete
Funding source
- Iran University of Medical Sciences

Expected recruitment start date
2007-03-20, 1385/12/29
Expected recruitment end date
2008-03-19, 1386/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of breast feeding, sucking the pacifier and being in mother’s hug on pain during infant’s immunization injection

Public title
Comparison of the effect of breast feeding, sucking the pacifier and being in mother’s hug on pain during infant’s immunization injection

Purpose
Prevention

Inclusion/Exclusion criteria
- Inclusion/Exclusion: 1. neonate should be awake 2. Neonate pad shouldn't be wet 3. neonate used to breast feed and suck pacifier 4. Neonate or its mother shouldn't use sedative drugs for 48 hours 5. Neonate shouldn't be fed 30 minutes before DPT vaccination 6. Neonate shouldn't be hospitalized for disease or surgery.
- Minimum age: 2 month, Maximum age: 4 month

Age
To 1 year old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 152
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Hemmat highway
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
498

Health conditions studied

1
Description of health condition studied
prevention of pain
ICD-10 code
Z00-Z99
ICD-10 code description
Factors influencing health status and contact with health services

Primary outcomes

1
Description
pain relieving
Timepoint
2 minutes before, during, and 15 seconds after the injection
Method of measurement
Modified Behavioral Pain Scale

Secondary outcomes
empty

Intervention groups

1
Description
First group were breast-fed, 2 minutes before, during, and 15 seconds after the injection
Category
Prevention

2
Description
Third group were in their mother's hug 2 minutes before, during, and 15 seconds after the injection
Category
Prevention

3
Description
Second group were used pacifier while held by mothers, 2 minutes before, during, and 15 seconds after the injection
Category
Prevention

4
Description
Control group according to routine clinic lied on the examining table
Category
N/A

Recruitment centers

1
Recruitment center
Name of recruitment center
Health centers in west of Tehran
Full name of responsible person
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
DR. Seid Abbas Motevalian
Street address
Hemmat highway, near Milad Hospital
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Shadab Shahali
Position
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty